

Application No. 10/092,954
Amendment dated 8/30/05
After Final Office Action of 6/1/05

Docket No.: 022719-0023RCE

AMENDMENTS TO THE CLAIMS

This Listing of Claims will replace all prior versions, and listings, of claims in this application.

Listing of Claims:

1. (Previously Presented) An implantable drug delivery system, comprising:
 - an infusion pump including a fluid outlet;
 - a fluid delivery line effective for extending from the fluid outlet to a discharge portion positionable at a target tissue site; and
 - a controlled release drug assembly downstream from the infusion pump, said drug assembly being configured for controllably releasing drug material, and communicating with said fluid delivery line such that the drug material is released into said fluid delivery line,wherein the pump assembly is effective to deliver a carrier fluid to the fluid outlet such that the drug material released into the delivery line discharges at the discharge portion to treat the target tissue site.
2. Withdrawn.
3. (Original) The system of claim 1, wherein the pump includes a chamber for holding a predetermined quantity of carrier fluid.
- 4.-6. Withdrawn.
7. (Previously presented) The system of claim 1, wherein the controlled release drug assembly is a microchip having at least one drug reservoir, and wherein the microchip is in fluid communication with the fluid delivery line intermediate to the pump and the target tissue site.
8. (Previously presented) The system of claim 7, wherein the microchip is located in the fluid delivery line.

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9. Withdrawn.

10. (Original) The system of claim 1, wherein the carrier fluid is a fluid selected from the group consisting of a physiological buffer, a pharmaceutical excipient or adjuvant, an endogenous fluid, and combinations thereof.

11. (Original) The system of claim 10, wherein the carrier fluid is an endogenous fluid selected from the group consisting of cerebral spinal fluid, blood, lymphatic fluid, components thereof, and combinations thereof.

12.-13. Withdrawn.

14. (Original) The system of claim 1, wherein the infusion pump includes a microcontrol unit that controls flow rate of the pump.

15. (Original) The system of claim 1, wherein the infusion pump is effective to pump at a rate to drive convection-enhanced transport into the target tissue site, thereby enhancing effective delivery profile at the target site.

16. (Original) The system of claim 1, wherein the flow rate ranges from about 0.5 to about 20 microliters per minute.

17. (Original) The system of claim 1, wherein the pump assembly includes a pump assembly selected from among the group consisting of a pressurized reservoir, a peristaltic pump, a diaphragm pump, and a piston pump.

18. Withdrawn.

19. (Original) The system of claim 1, wherein the drug release assembly includes a microchip powered by a power source.

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20. (Original) The system of claim 14, wherein the microchip is in communication with the microcontrol unit.

21. Withdrawn.

22. (Original) The system of claim 1, wherein the drug release assembly includes a microchip containing one or more drugs therein.

23.-24. Withdrawn.

25. (Original) The system of claim 1, wherein the drug release assembly is a microchip having a plurality of reservoirs containing plural different drugs, drug concentrations, or a combination thereof.

26.-27. Withdrawn.

28. (Original) The system of claim 1 further comprising an array of biosensors disposed in tissue, and wherein at least one of the infusion pump and the controlled drug release assembly responds to biosensor signals from the array.

29. (Previously Presented) A method for infusing a drug into a target tissue site of a subject, the method comprising the steps of:

providing an infusion pump assembly, wherein the pump assembly includes a carrier fluid source, wherein the infusion pump assembly is effective to convey a fluid within the pump through a fluid delivery line to a discharge portion positionable at a target tissue site;

providing an implantable drug release assembly in communication with the fluid delivery line and downstream from the infusion pump, said release assembly having at least one drug reservoir configured for controlled release of a drug into the fluid delivery line; and

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enabling a carrier fluid to be delivered under pressure from the infusion pump assembly at a desired flow rate through the fluid delivery line to transport drug released by the drug release assembly to the target tissue site.

30. (Original) The method of claim 29, wherein the pump assembly is effective to deliver carrier fluid at a rate effective to induce convective bulk transport of the drug into tissue at the target site.

31. (Original) The method of claim 30, wherein the target site is brain tissue and the pump assembly is effective to deliver carrier fluid at a rate in the range of about 0.5 to about 20 microliters/minute to induce convective bulk transport of the drug into brain tissue.

32. (Previously presented) The method of claim 29, wherein the fluid delivery line terminates in a distal end, wherein the distal end is implantable within the target site.

33. (Original) The method of claim 29, wherein the one or more drugs are released in a delivery regimen selected from among a pulsatile, an intermittent and a continuous delivery regimen.

34. (Previously presented) The method of claim 29, further including the step of providing a biosensor in at least one of the fluid delivery line, the tissue site and the controlled release assembly, and controlling at least one of the infusion pump assembly and the drug release assembly in response to biosensor signals.

35. (Original) The method of claim 29, further including the step of detecting a material or condition with a biosensor array, and controlling at least one of the infusion pump assembly and the drug release assembly in response thereto.

36. (Original) The method of claim 29, wherein the carrier fluid is selected from the group consisting of a physiological buffer, a pharmaceutical excipient or adjuvant, an endogenous fluid, and combinations thereof.

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37. (Original) The method of claim 29, wherein the carrier is an endogenous fluid selected from the group consisting of cerebral spinal fluid, blood, lymphatic fluid, components thereof, and combinations thereof.

38. (Original) The method of claim 29, wherein the infusion pump assembly is operable to continuously maintain enhanced fluid pressure over a predetermined period of time.

39. (Original) The method of claim 29, wherein a microcontrol unit disposed within the infusion pump controls fluid delivery pressure profile over a predetermined period of time.

40. (Previously Presented) A method of delivering a drug or bioactive material to target tissue such as tissue of the central nervous system (CNS), such method comprising the steps of
providing an infusion pump having an output connectable with a delivery line implantable at a target tissue site; and

providing an implantable controlled release drug device attachable downstream from the infusion pump and in communication with the delivery line, such that the controlled release drug device is effective to release drug into carrier fluid pumped by the infusion pump;

thereby delivering the carrier fluid to the target tissue site with said drug, the pump being controllable to maintain an elevated delivery pressure such that the drug achieves a convectively enhanced profile in tissue at the target tissue site.